SDA 40B- alcohol solution Mann Lake Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Sani-Effect Gel Hand sanitizer Fresh Scent with Viatmin E and Aloe Vera

This is a hand sanitizer.

Active Ingredient(s)

Alcohol 70% v/v. Purpose Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Di not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control center right away.

Directions

- Place enough product on the hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

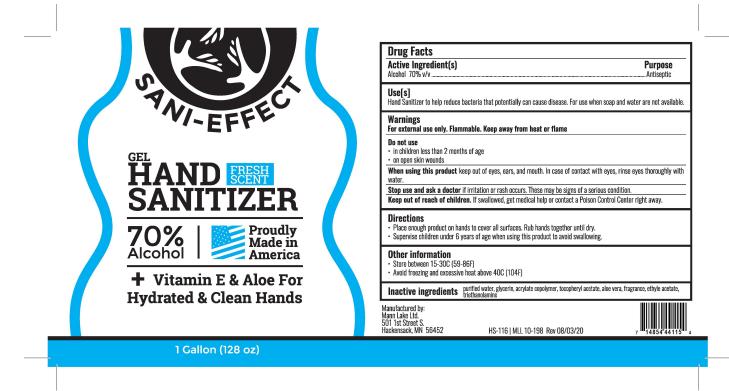
Other Information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

glycerin, triethanolamine, carbomer, ethyl acetate, vitamin E, aloe vera, fragrance, purified water USP

8019-0116-1



80194-116-2



Purpose Antiseptic

SDA 40B									
alcohol solution									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Sou		NDC:		80194-0116			
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
Ingredient Name			Basis of Strength		gth	Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL			70 L in 100 L			
Inactive Ingredients									
Ingredient Name				Strength					
WATER (UNII: 059QF0KO0R)				30 L in 100 L					

P	Packaging							
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:80194- 0116-1	3.78 L in 1 PACKAGE; Type 0: Not a Combination Product	08/19/2020					
2	NDC:80194- 0116-2	0.236 L in 1 PACKAGE; Type 0: Not a Combination Product	08/19/2020					
Marketing Information								
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
01 fin	۲C monograph no al	t part333A	08/19/2020					

Labeler - Mann Lake Ltd (121181846)

Registrant - Mann Lake LTD (121181846)

Establishment

Name	Address	ID/FEI	Business Operations
Mann Lake Ltd		121181846	manufacture(80194-0116)

Revised: 8/2022

Mann Lake Ltd